

U.S. Patent Application Serial No.: 10/761,505  
Amendment dated November 13, 2006  
Official Action dated June 13, 2006

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**REMARKS**

The Official Action dated June 13, 2006 has been carefully considered. It is believed that the present Amendment, together with the Terminal Disclaimer submitted herewith, are sufficient to place the present application in condition for allowance. Reconsideration is respectfully requested.

By the present Amendment, the specification is amended to include customary section headings and to present the Brief Description of the Drawings in accordance with customary U.S. patent practice. Claim 15 is amended to include the limitation of claim 16, to include the analogue definition set forth at page 1, lines 21-22 of the specification, and to further define the patient in accordance with the teachings of the specification at page 5, lines 16-18. It is believed that these changes do not involve any introduction of new matter, whereby entry is believed to be in order and is respectfully requested.

In the Official Action, claims 15-22 were rejected on the ground of nonstatutory obviousness-double patenting as being unpatentable over claims 1-5 of U.S. Patent No. 6,696,414. This rejection is traversed. However, to expedite prosecution, submitted herewith is a Terminal Disclaimer which disclaims the terminal part of the statutory term of any patent issuing on the present application which would extend beyond the expiration date of the full statutory term of U.S. Patent No. 6,696,414, as set forth in the Terminal Disclaimer. The filing of a Terminal Disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither presumption nor estoppel on the merits of the rejection. *Quad Environmental Technologies v. Union Sanitary District*, 20 U.S.P.Q. 2d 1392 (Fed. Cir. 1991). It is therefore believed that the rejection of the claims on the ground of nonstatutory obviousness-double patenting has been overcome. Reconsideration is respectfully requested.

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Claims 15-22 were rejected under 35 U.S.C. §112, first paragraph, on the basis that the specification, while enabling for a method of increasing insulin sensitivity in a normal subject by administering growth hormone or an analogue of growth hormone having an additional methionine residue at the N-terminal in a low dose, does not reasonably provide enablement for a method of increasing insulin sensitivity in a patient by administering growth hormone or an analogue of growth hormone in a low dose.

This rejection is traversed with respect to claims 15 and 17-22 presented herein. Particularly, claim 15 recites a method for increasing insulin sensitivity in a non-obese person who is prone to developing type 2 diabetes and syndrome X in accordance with the teachings in the specification, for example at page 5, lines 13-19. Further, the method of claim 15 comprises the administration of growth hormone or growth hormone analogue having an additional methionine residue at the N-terminal end. The present specification describes preparations of both growth hormone and the claimed analogue at page 1, lines 20-22. It is therefore believed that the present specification enables a method of claim 15, and claims 17-22 dependent thereon, in accordance with the requirements of 35 U.S.C. §112, first paragraph, whereby the rejection has been overcome. Reconsideration is respectfully requested.

Finally, claims 15 and 17-19 were rejected under 35 U.S.C. §102(b) as being anticipated by the Johannsson PCT Application WO 97/38709. The Examiner asserted that Johannsson discloses a method of administering human growth hormone to male subjects with abdominal/visceral obesity.

This rejection is traversed and reconsideration is respectfully requested. More particularly, claim 15, as noted above, is directed to a method of increasing insulin sensitivity in a non-obese patient who is prone to developing type II diabetes and syndrome X. The method comprises the

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administration of growth hormone or growth hormone analogue having an additional methionine residue at the N-terminal end to the patient in a low dose.

On the other hand, as noted by the Examiner, Johannsson discloses a method of administering human growth hormone to male subjects with abdominal/visceral obesity. Applicant finds no teaching or suggestion by Johannsson relating to methods for increasing insulin sensitivity in a non-obese patient as recited in the present claims.

Anticipation under 35 U.S.C. §102 requires that each and every element as set forth in the claims is found, either expressly or inherently described, in a single prior art reference. *In re Robertson*, 49 U.S.P.Q. 2d 1949, 1950 (Fed. Cir. 1999). In view of the failure of Johannsson to disclose a method for increasing insulin sensitivity in a non-obese patient, Johannsson does not disclose each and every element as set forth in the present claims, and therefore does not anticipate the present claims under 35 U.S.C. §102. Accordingly, the rejection under 35 U.S.C. §102 based on Johannsson has been overcome. Reconsideration is respectfully requested.

It is believed that the above, together with the Terminal Disclaimer submitted herewith, overcome the rejections under 35 U.S.C. §§102 and 112, first paragraph, and the rejection on the ground of nonstatutory obviousness-double patenting, and places the present application in condition for allowance. Reconsideration and an early allowance are requested.

Respectfully submitted,

  
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